

Appl. No. 09/963,347

Remarks***I. Status Of The Claims***

Claim 21 has been canceled. Claim 33 is pending.

Support for the amendment of claim 33 is found in application no. 09/963,347 ("the present application") at page 31, line 8.

Support for claim 33 is found in priority application no. 60/101,318, filed September 21, 1998 ("the '318 application") at page 7, lines 3-6; page 19, lines 23-24 and 30-31; page 32, line 34; page 33, lines 16, 17 and 22; and original claim 16.

No new matter has been added by this amendment.

***II. The Lack Of Novelty Rejection Should Be Withdrawn***

Claims 21 and 33 stand rejected under 35 U.S.C. § 102(e) as allegedly lacking novelty over U.S. Patent No. 6,555,520 ("the '520 patent"). Applicants respectfully traverse this rejection.

Claim 21 has been canceled. Regarding claim 33, Applicants provide the following remarks.

***A. The Alleged Basis For The Rejection Is Improper***

Underlying the lack of novelty rejection is the allegation that, because the '318 application allegedly fails to disclose a utility for the claimed invention, the claimed invention does not have priority to the '318 application, with the result that the '520 patent is allegedly prior art against the claimed invention. According to the Examiner:

Because the specific, substantial and credible utility of the instant IL-B50 polypeptides is only disclosed in the instant application, the effective filing date for the instant invention is determined as the filing date of the instant application (09/25/2001), which makes the patent of Sims et al. a proper 102(e) reference."

Office Action mailed May 11, 2006 at pages 2-3.

Applicants respectfully disagree with the Examiner's conclusion that the '318 application fails to provide utility for the claimed invention. Utility for the claimed invention is disclosed in the '318 application. Moreover, a *prima facie* case of lack of utility has not been established. As a result, the lack of novelty rejection is improper.

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**1. Utility For The Claimed Invention Is Disclosed In The '318 Application****a. The Disclosed Utility Is Specific**

Because the threshold of utility is not high under 35 U.S.C. § 101, an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999). In other words, only a minimal utility is required. Here, the disclosure in the '318 application is sufficient to meet the minimal utility standard set forth in 35 U.S.C. § 101.

At least one specific utility has been disclosed in the '318 application for the polypeptide encoded by the nucleic acid molecule having SEQ ID NO: 1, *i.e.*, IL-B50. For example, the '318 application discloses that IL-B50 is likely to have stimulatory or inhibitory effects on hematopoietic cells, including *e.g.*, lymphoid cells, such as T-cells, B-cells, natural killer cells, macrophages, dendritic cells, and hematopoietic progenitors. *See* the '318 application at page 9, lines 9-13. The '318 application also discloses that IL-B50 may also be useful in the treatment of immune disorders, *e.g.*, T cell immune deficiencies, chronic inflammation, or tissue rejection, or in cardiovascular or neurophysiological conditions. *See* the '318 application at page 13, lines 1-4.

The '318 application also discloses that IL-B50 and IL-7 are likely to share similar biological functions, (*see* page 12, lines 1-4), and that IL-7 exhibits strong effects on lymphopoietic development and differentiation (*see* page 59, lines 21-22). The '318 application also discloses that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another receptor subunit (*see* page 49, lines 25-28).

Evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility is supportive of an assertion of therapeutic utility for a new compound. M.P.E.P. § 2107.03, part II. One of ordinary skill in the art would have understood from the '318 application that the polypeptide encoded by the nucleic acid molecule having SEQ ID NO: 1 has similar functions as IL-7, such as stimulating lymphopoietic development and differentiation.

**b. The Disclosed Utility Is Substantial**

According to the M.P.E.P., "[c]ourts have repeatedly found that the mere *identification* of a pharmacological activity of a compound is relevant to an asserted pharmacological use provides an 'immediate benefit to the public' and satisfies the utility requirement." M.P.E.P. § 2107.01, part III.

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Here, the identification of the polypeptide encoded by SEQ ID NO: 1 as having an effect on hematopoietic cells and having a role in treating immune disorders provides researchers and physicians with a new target for intervention in immune disorders and disease. As a result, the claimed polypeptide has a "real world" use. Therefore, the utility disclosed in the '318 application for the polypeptide encoded by SEQ ID NO: 1 is substantial.

***c. The Disclosed Utility Is Credible***

An assertion of utility is credible *unless* the logic underlying the assertion is seriously flawed or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. *See* M.P.E.P. § 2107.02, part III.B. Here, the utility asserted in the '318 application is credible, because of the sequence similarity between IL-7 and the polypeptide encoded by SEQ ID NO: 1.

***2. A Prima Facie Case Of Lack Of Utility Has Not Been Established***

An asserted utility creates a presumption of utility. *See* M.P.E.P. § 2107.02, part III.A. The M.P.E.P. also cautions that "Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons." *Id.* Rather, "any inquiry must start by asking if there is any reason to question the truth of the statement of utility." *Id.*

Indeed, the Examiner bears the initial burden of showing that a claimed invention lacks utility. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence . . ."); and *see* M.P.E.P. § 2107.02, part IV.

At page 3 of the Office Action mailed May 11, 2006, the Examiner refers the reader to a "detailed analysis" at section 8 of the Office Action mailed August 2, 2004, and section 7 of the Office Action mailed February 4, 2005.

In section 8 (at page 8) of the Office Action mailed August 2, 2004, the Examiner explained simply:

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Because the '318 application fails to disclose specific utility of IL-B50 ("either stimulatory or inhibitory effect" does not provide for specific activity), and because the specific, substantial and credible utility of the instant IL-B50 is only disclosed in the instant specification, the effective filing date for the instant invention remains the filing date of the instant application, 09/25/2001, which makes "the Sims patent" ["the '520 patent] proper 102(e) reference.

In section 7 (at page 6) of the Office Action mailed February 4, 2005, the Examiner reiterated the above statement, and added:

Also, the fact that the instant claimed IL-B50 has sequence similarity to the IL-7 class of molecules does not automatically "assign" a specific function to the novel IL-B50. Numerous publications exist on topic of predicting protein functions from structural similarities or homology to the known proteins. It is well settled in the art that functional characteristics of a protein cannot be unequivocally extrapolated from its structural characteristics. Moreover, in the instant case, because the spectrum of activities of IL-7 is not limited to one single function, there appears to be no real possibility of reasonable prediction which one of IL-7 activities supports the practical utility of the claimed IL-B50.

Here, the reasons proffered by the Examiner are not sufficient to establish that one of ordinary skill in the art would reasonably doubt that the utility set forth in the '318 application is correct. Moreover, the Examiner's proffered reasons are conclusory, and are not supported by any evidence. Thus, the burden has not shifted to Applicants to rebut a *prima facie* case of lack of utility.

Absent the establishment of a *prima facie* case of lack of utility, the allegation that the claimed invention is not entitled to priority in the '318 application is improper.

#### **B. Summary**

Utility for the claimed invention is disclosed in the present application and in the '318 application. A *prima facie* case of lack of utility has not been established.

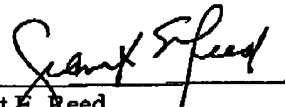
The claimed invention has priority to the '318 application. As a result, the '520 patent is not available as prior art. Applicants respectfully request that this rejection be reconsidered and withdrawn.

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Conclusion

It is believed that each of the objections and rejections in the Office Action have been addressed.

Respectfully submitted,

  
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